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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,964	12/15/2005	Jurgen Dorn	480052000900	1085

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EXAMINER	
YABUT, DIANE D	
ART UNIT	**PAPER NUMBER**
3734	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,964	DORN, JURGEN	
	Examiner	Art Unit	
	Diane Yabut	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 15 February 2006 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because:
> It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

Specification

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-8 and 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by **Dwyer** (U.S. Pub. No. **20020016597**).

Claim 1: Dwyer discloses an inner catheter **12** ("shaft") and a sheath **14** disposed around at least a portion of the inner catheter, the sheath being retractable in a proximal direction relative to the inner catheter, the inner catheter configured to resist a radially inward contraction of the sheath arising from the application of an endwise tensile stress to a proximal end of the sheath (Figures 2 and 5-9; page 4, paragraph 39).

Claims 2-4: Dwyer discloses a lubricious fluid coating on an outer surface of the inner catheter **12** and in the annulus between the sheath **14** and the inner catheter, the sheath comprising a thermoplastic elastomeric material (page 3, paragraph 20 and page 5, paragraph 43).

Claim 5: Dwyer discloses the inner catheter comprising a wire coil **24** having a lumen, a distal end, a proximal end, a distal region, an intermediate region and a proximal region and an outer tube **46** disposed around at least a portion of the wire coil (page 4, paragraphs 39-40).

Claim 6: Dwyer discloses the inner catheter including an inner tube in the wire coil lumen (Figures 2-3).

Claim 7: Dwyer discloses the distal end of the inner tube extends to a point distal of the distal end of the wire coil (Figures 2-3).

Claim 8: Dwyer discloses the inner tube defining an inner guidewire lumen **34** (Figure 4, page 4, paragraph 36).

Claims 13-14: Dwyer discloses the outer tube **46** being a shrink-tube constraining the wire coil and comprising PTFE (page 4, paragraph 40).

Claim 15: Dwyer discloses the inner tube defining a medical-device-receiving annulus ("stent bed") **42** around a distal portion of the inner tube, said distal region being distal of the distal end of the wire coil and proximal of the distal end of the inner tube (Figure 2, page 4, paragraph 38).

Claim 16: Dwyer discloses an atraumatic tapered tip **28** positioned at the distal end of the catheter (Figure 2).

Claim 17: Dwyer discloses the tip **28** being formed as part of the sheath (page 5, paragraph 41).

Claim 18: Dwyer discloses the tip **28** being attached to the inner catheter (Figure 2).

Claim 19: Dwyer discloses the tip **28** comprising polyurethane (page 3, paragraph 34).

Claim 20: Dwyer discloses an actuating device **58** connected to a proximal end of the inner catheter and the sheath configured to retract the sheath in a proximal direction relative to the inner catheter (Figures 1, 5-9 and page 6, paragraph 50).

Claim 21: Dwyer discloses a medical device **100** maintained in position between the sheath and the inner catheter, the medical device being releasable by retraction of the

sheath in a proximal direction relative to the inner catheter (Figures 1, 5-9 and page 6, paragraph 50).

Claim 22: Dwyer discloses the medical device being held within the lumen of the sheath at a location distal of the distal end of the wire coil, the medical device being maintained radially compressed in a first state by the sheath being disposed around at least a portion of the medical device, during retraction of the sheath the medical device is prevented by the wire coil from moving with the sheath in a proximal direction and when the sheath is retracted in a proximal direction relative to the inner catheter, the medical device is released for expansion to a radially less compress state (Figures 1, 5-9 and page 6, paragraph 50).

Claim 23: Dwyer discloses the medical device being a self-expanding stent **100** (page 5, paragraph 44).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 9-12, 24-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Dwyer** (U.S. Pub. No. **20020016597**), as applied to Claim 5 above, and further in view of **Wijay** (U.S. Patent No. **5,690,643**).

Claims 9-12: Dwyer discloses the claimed device, including a wire coil having a closed-coil structure in the intermediate region, except for the wire coil having a closed-coil structure in the intermediate region and an open-coil structure in at least one or both of the distal region and the proximal region, and the wire coil defining a liquid flow path from the proximal end to the distal end of the catheter including a radially-extending portion through the open-coil structure and an annular flow path bounded by the inner tube and the wire coil.

Wijay teaches an open-coil structure **36** in at least one of the distal region and the proximal region defining a liquid flow path from the proximal end to the distal end of a catheter including a radially-extending portion through the open-coil structure and an annular flow path bounded by the inner tube and the wire coil, in order to permit perfusion to the device so that drugs or blood can be carried through which reduces patient discomfort (Figure 5, col. 4, lines 1-11 and 37-42). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an open-coil structure, as taught by Wijay, to Dwyer in order to permit perfusion and reduce patient discomfort. Although Wijay does not disclose the open-coil structure in both the proximal and distal ends, it would have been obvious to one of ordinary skill in the art to do so for increasing perfusion evenly throughout the device.

Claim 24: Dwyer discloses a catheter, including an inner catheter and a sheath, the inner catheter including an inner polymeric tube, a wire coil disposed about a portion of the inner tube, an annular gap between the inner polymeric tube and wire coil, the sheath disposed about the inner catheter, and an actuating device connected to the

catheter (see paragraph 5 above), except for the wire coil including an open-coil structure in at least one of a proximal region and a distal region and a closed coil structure in an intermediate region.

Wijay teaches the wire coil including an open-coil structure in at least one of a proximal region and a distal region and a closed coil structure in an intermediate region in order to permit perfusion to the device so that drugs or blood can be carried through which reduces patient discomfort (Figure 5, col. 4, lines 1-11 and 37-42). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an open-coil structure, as taught by Wijay, to Dwyer in order to permit perfusion and reduce patient discomfort.

Claims 25-26: Dwyer discloses the catheter including an outer tube **46** disposed about the wire coil, including the intermediate region, and being a shrink-tube constraining the wire coil and comprising PTFE (page 4, paragraphs 39-40).

Claims 27-28: Dwyer discloses the outer tube comprising PTFE and wherein a silicone coating is siposed over a surface of the outer tube, and the sheath comprising a thermoplastic elastomer and is in contact with the silicone coating (page 3, paragraph 20, page 4, paragraphs 39-40 and page 5, paragraph 43).

Claims 29-30: Dwyer discloses a distal end of the wire coil being joined to a pusher element **40** disposed about a distal region of the inner tube that includes a shoulder, and a stent bed **42** being defined along a distal region of the inner tube between the shoulder and a distal end of the inner tube (Figure 2, page 6, paragraph 50).

Claim 31: Dwyer discloses a tip **28** attached to the distal end of the inner tube **12**, a distal end of the sheath **14** abutting the tip in a delivery apparatus insertion position (Figure 5).

Claim 32: Dwyer discloses a push rod disposed about the inner tube at a proximal region thereof, a distal end of the push rod joined to a proximal end of the wire coil (page 1, paragraph 8; page 2, paragraph 13).

Claim 34: Dwyer discloses the actuating device **58** including a first member connected to the inner catheter and a second member connected to the sheath, the second member including a locking member configured to prevent relative movement between the inner catheter and the sheath (page 6, paragraphs 49-50).

Claim 35: Dwyer discloses an open position of the actuating device includes the first member spaced apart from the second member and wherein a closed position of the actuation gdevice includes the first member adjacent to the second member (page 6, paragraphs 49-50).

Claim 36: Dwyer discloses the second member including a luer member in fluid communication with the inner catheter (page 6, paragraphs 49-50).

8. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Dwyer** (U.S. Pub. No. **20020016597**) and **Wijay** (U.S. Patent No. **5,690,643**) as applied to Claim 24 above, and further in view of **Klemm** (U.S. Patent No. **5,458,615**).

Claim 33: Dwyer and Wijay disclose the claimed device except for a radiopaque marker band being attached to an inner surface of a distal end of the sheath.

Klemm teaches a radiopaque marker band being attached to an inner surface of a distal end of a sheath so that the physician can determine when the sheath has been withdrawn a sufficient distance so as not to interfere with the deployment of the stent (col. 9, lines 25-35). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a radiopaque marker on the sheath, as taught by Klemm, to Dwyer and Wijay in order to avoid interference with the deployment of the stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER